



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

January 27, 2016

I, Richard Gebken, Invertebrate and Vertebrate Branch 2, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Lebanon) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Bayer Cropscience Lp  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park, NC 27709

EPA Registration Number: 264-1025  
Name of Product: BELT SC INSECTICIDE

Richard Gebken  
Risk Manager 10  
Invertebrate and Vertebrate Branch 2  
Registration Division (7505P)



Receipt for Section 3

S: 979588

Milestone Email:

RICHARD GEBKEN

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 264 BAYER CROPSCIENCE LP

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 10

Product #: 264-1025

Product Name: BELT SC INSECTICIDE

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 06-Jan-2016



OPP Rec'd Date: 11-Jan-2016



Front End Date: 12-Jan-2016



Risk Manager Send Date: 12-Jan-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Gold Seal Certificate for Lebanon

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Other

Gold Seal

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 12, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-512806  
EPA File Symbol or Registration Number: 264-1025  
Product Name: BELT SC INSECTICIDE  
EPA Receipt Date: 11-Jan-2016  
EPA Company Number: 264  
Company Name: BAYER CROPSCIENCE LP

NATALIE MAUCHMAR  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, PO Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

A handwritten signature in black ink, appearing to be "N. Williams", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Bayer CropScience LP	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Belt SC Insecticide	PM#	
5. Name and Address of Applicant (Include ZIP Code)  Natalie Mauchmar 2 T.W Alexander Drive Office 1177 Durham, NC 27709  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-1025 Product Name Belt SC Insecticide	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Gold Seal Certificate  
Gold Seal Certificate for Lebanon

Thank you!!

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Natalie Mauchmar		Title Labeling Specialist	
		Telephone No. (Include Area Code) 919-549-2350	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)
2. Signature		3. Title Labeling Specialist	
4. Typed Name Natalie Mauchmar		5. Date 01/06/2016	



**MAKE A PAYMENT****FIND AN AGENCY****ONLINE HELP**

Find Forms, Agencies...

Search

For your security, we recommend you close your browser when you complete your payment.

## Payment Confirmation - Pesticide Registration Improvement Act - Prepayment

Before You Begin    1 Complete Agency Form    2 Enter Payment Info    3 Review & Submit  
4 Confirmation

### Need Help?

PRIA Service Fees

Contact: Michael

Yanchulis

Email: [Click to email](#)

Phone: (703) 347-0237

### Payment Confirmation

Your payment is complete

Pay.gov Tracking ID: 25P8EBCD

Agency Tracking ID: 74936008046

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

#### Payment Information

Payment Type: Debit or credit card

Payment Amount: \$554.00

Transaction Date: 01/05/2016 08:02:56 PM EST

Payment Date: 01/05/2016

Registration Number: 264-1025 264-709

Company Name: Bayer Crop Science

Company Number: 264

Action Code: M006

#### Account Information

Card Holder Name: Natalie Mauchmar

Card Type: Master Card

Card Number: \*\*\*\*\*9829

#### Email Confirmation Receipt

Confirmation Receipts have been emailed to:

natalie.mauchmar@bayer.com

[Print Receipt](#)**Register today!**

Recommendation of Division Directors Negotiated Due Dates			
Decision #: 491208		Registration #: 264-1025	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Flubendiamide			
Fee Category: R350		PRIA Decision Time Frame: 9 Months	
Submitted by: Carmen Rodia		Branch: OCSPP/OPP/RD	Date: 08/26/2015
Company: Bayer CropScience LP			
Original PRIA Due Date: 03/03/2015		Proposed New PRIA Due Date: 05/31/2016	
Previous Negotiated Due Dates: 08/30/2015 06/01/2015			
Is the "Fix" in-house? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a		If not, date "Fix" expected:	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Efficacy	<input type="checkbox"/> Toxicology <input type="checkbox"/> Ecological	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Residue <input type="checkbox"/> Environmental <input type="checkbox"/> Other
Data Deficiencies	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Environmental	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Ecological	<input type="checkbox"/> Efficacy <input type="checkbox"/> Labeling <input type="checkbox"/> Residue <input type="checkbox"/> Other <input type="checkbox"/> Toxicology <input type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological		
Interim Consideration	<input type="checkbox"/> Agency Initiated <input checked="" type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Additional time is needed for HED to complete its review of the subject R350 PRIA action to reduce the PHI for tobacco use for flubendiamide.			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
As a follow-up on numerous discussions for the time-limited registration with BCS, the Agency ask BCS to withdraw the pending submissions that expand the outdoor uses of this AI. Earlier in the year Susan placed all pending actions on hold. This request will allow this action to move forward to review with HED.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Additional time is needed to complete review of subject R350 action.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 08/27/2015

<b>Decision #:</b> 491208	<b>Registration #:</b> 264-1025	<b>Petition #:</b>

**Issue(s) (describe in detail):**

As part of ongoing discussions with the registrant (BCS) related to the time limited registration of flubendiamide since the "hold as now be lifted" additional time is needed for HED to complete its review of the subject R350 PRIA action to reduce the PHI for tobacco use for flubendiamide. Carmen Rodia contacted BCS via teleconference call (August 26, 2015) informing BCS that EPA will require an extended PRIA conclusion date to provide HED with additional time to complete the referenced R350 review. On August 26, 2015, BCS informed Carmen Rodia that they have agreed to an extension of the existing PRIA conclusion date, and formally requested (copy attached) that the PRIA conclusion date be extended 9 months from August 30, 2015 to May 31, 2016.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15238124850-CR

SUBMITTED on 08/26/2015 at 12:55:38 PM by CN=Carmen Rodia/OU=DC/O=USEPA/C=US

APPROVED on 08/26/2015 at 03:00:35 PM by CN=Deborah McCall/OU=DC/O=USEPA/C=US

APPROVED on 08/26/2015 at 05:16:36 PM by CN=George Herndon/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 08/27/2015 at 06:48:45 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

August 25, 2015


I, Richard Gebken, Invertebrate and Vertebrate Branch 2, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Kenya) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Bayer Cropscience Lp  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park, NC 27709

EPA Registration Number: 264-1025  
Name of Product: BELT SC INSECTICIDE

  
Richard Gebken  
Risk Manager 10  
Invertebrate and Vertebrate Branch 2  
Registration Division (7505P)





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Bayer CropScience LP	2. EPA Product Manager RICHARD GERKEN	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BELT SC Insecticide	PM#	
5. Name and Address of Applicant (Include ZIP Code)  Natalie Mauchmar 2 T.W Alexander Drive Office 1177 Durham, NC 27709  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-1025 Product Name BELT SC Insecticide	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Gold Seal Certificate for Kenya

Thank you!!

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Natalie Mauchmar		Title Labeling Specialist	
		Telephone No. (Include Area Code) 919-549-2550	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature		3. Title Labeling Specialist	
4. Typed Name Natalie Mauchmar		5. Date 08-13-2015	

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, DC 20460.**

**INSTRUCTIONS:** This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

**Submission of Labeling** -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**Section I** - The section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your company number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** -This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. **Subject of submission** -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use"; "notification for...". Attach a separate page if additional space is needed.

**SECTION III** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packages and number per retail container.
2. **Type of Retail Container** -Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicate the method product label is attached to retail container.

**SECTION IV (Contact Point)** -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory
6. EPA Use Only



Receipt for Section 3

S: 972774

Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 264 BAYER CROPSCIENCE LP

Resubmission: ☐ Yes ☒ No

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 10

Product #: 264-1025

Product Name: BELT SC INSECTICIDE

Override#

Me Too Section3:

Me Too Product Name:

Application Date: 13-Aug-2015

Front End Date: 17-Aug-2015

FFS Due Date:

OPP Target Date:

OPP Rec'd Date: 17-Aug-2015

Risk Manager Send Date: 17-Aug-2015

Negotiated Due Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Gold Seal Certificate for Kenya.

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Other

Gold Seal

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

Signature Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 17, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-508068  
EPA File Symbol or Registration Number: 264-1025  
Product Name: BELT SC INSECTICIDE  
EPA Receipt Date: 17-Aug-2015  
EPA Company Number: 264  
Company Name: BAYER CROPSCIENCE LP

NATALIE MAUCHMAR  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, PO Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

A handwritten signature in black ink, appearing to be "m/zh".

Front End Processing Staff  
Information Technology & Resources Management Division

BNY MELLON, N.A.  
PITTSBURGH 15262



**Bayer**  
Pittsburgh, PA 15285

Contact for Question.  
1-866-283-6752

CHECK NO.3200230424

60-160  
433

PAY:

\*\*\*TWO HUNDRED SIXTY-THREE AND 00/100  
DOLLARS\*\*\*

VOID 180 DAYS AFTER DATE OF CHECK

DATE:06-23-15 \$\*\*\*\*\*263.00

TO  
THE  
ORDER  
OF

ENVIRONMENTAL PROTECTION AGENCY  
USEPA WASHINGTON FINANCE CENTER  
PESTICIDE REGISTRATION SERVICE  
PO BOX 979074  
ST. LOUIS MO 63197-9000

Authorized Signatures

*Gray J. Samuel*  
*Daniel J. Allen*



3200230424



**Bayer**  
Pittsburgh, PA 15285

Contact for Questions  
1-866-283-6752

PBC/528 BEPRW

VENDOR NO.		VENDOR NAME		DATE	CHECK NO.	CHECK AMOUNT
6768799		Environmental Protection Agency		06-23-15	3200230424	263.00
REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT		NET AMOUNT
IP16061510332949 Gold Seal Certificate	06-16-15	2400501625	263.00	0.00		263.00

## Rodia, Carmen

---

**From:** Rodia, Carmen  
**Sent:** Wednesday, August 26, 2015 2:08 PM  
**To:** Schaible, Stephen  
**Subject:** For E-Signature: PRIA Withdrawal for EPA Reg. Nos. 264-1025 & 71711-26  
**Attachments:** Flubendiamide, Confirmation of Withdraw (08-26-15).docx; Bayer.pdf

Steve, as part of EPA's ongoing discussions with the registrant (BCS) related to the conditional registration of flubendiamide and a potential path forward for this time-limited registration, it was mutually agreed that any pending applications to expand outdoor uses during the time-limited conditional period of registration would be withdrawn by BCS. This confirmation of BCS' withdraw of these actions is attached for your review and concurrence. If you have any questions related to this e-mail, please contact me directly. Regards, Carmen.

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Registration Division, Invertebrate & Vertebrate Branch 2  
1200 Pennsylvania Avenue, NW (7504P)  
Washington, DC 20460-0001  
(703) 306-0327 (tel)  
(703) 308-0029 (fax)  
[Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Date: August 26, 2015  
OPP Decision Numbers: 493617, 493618, 493619, 495233 & 495242  
EPA Registration Numbers: 264-1025 & 71711-26  
Petition Number: PP #4F8283  
Product Name: BELT™ SC Insecticide & FLUBENDIAMIDE Technical  
EPA Receipt Date: September 9, 2014  
EPA Company Number: 264  
Company Name: Bayer CropScience LP

Mrs. Nancy Delaney  
Regulatory Manager  
Authorized Agent for Nichino America, Inc.  
c/o Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, NC 27709-2014

Subject: Confirmation of Request to Withdraw an Application

Dear Mrs. Delaney:

This is to confirm that the Agency has received and processed your request of August 26, 2015 to withdraw the above referenced applications. Since we received your request to withdraw these applications more than 60 days from the beginning of the decision review period, the Agency has determined that based on the work completed at the time the application was withdrawn, 75% of the amount paid should be refunded to you as soon as practicable. Any future submission related to this action must be submitted as a new application that requires either the appropriate fee.

If you have questions concerning this letter, please contact the Pesticide Registration Fee Ombudsperson at (XXX) XXX-XXXX.

Sincerely,

## Rodia, Carmen

---

**From:** Nancy Delaney <nancy.delaney@bayer.com>  
**Sent:** Wednesday, August 26, 2015 11:26 AM  
**To:** Rodia, Carmen  
**Cc:** Frank Rittemann; Charlotte Sanson; BCSReg\_Archive  
**Subject:** Action Required: withdrawal of Bayer's flubendiamide open PRIA actions

Good morning Carmen,

Since Bayer has agreed to forego submission of any applications to expand outdoor uses during the time-limited and conditional period of registration, we are writing to request that EPA withdraw the following PRIA actions and reimburse Bayer 75% of the PRIA:

Registration/Petition Numbers	Description of PRIA/IR-4 Actions	Decision Numbers
71711-26 (FLUBENDIAMIDE TECHNICAL)	R170.2/R170.3; Establish Tolerances for Use on Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493617 and 495233
264-1025 (BELT SC Insecticide)	R170; Establish Tolerances for Use on Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493618 and 495242
PP #4F8283	R170; Establish Tolerances for Use on Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493619

Please let me know if there is something else you require to process this request.

Best Regards  
Nancy



**Bayer CropScience**  
Science For A Better Life

Nancy Delaney  
Federal Registrations  
Research Triangle Park, North Carolina, USA  
27709  
Phone: +1 919-549-2080  
Cell: 919-384-5957  
e-mail: [nancy.delaney@bayer.com](mailto:nancy.delaney@bayer.com)  
Web: [www.bayercropscience.ca](http://www.bayercropscience.ca)

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

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## Rodia, Carmen

---

**From:** Nancy Delaney <nancy.delaney@bayer.com>  
**Sent:** Wednesday, August 26, 2015 11:34 AM  
**To:** Rodia, Carmen  
**Cc:** Frank Ritemann; Charlotte Sanson; BCSReg\_Archive; BCSReg\_Archive  
**Subject:** Follow up: request for approval to extend the PRIA timeline for Bayer's R350 action to revise PHI in tobacco

Dear Carmen,

Pardon my error in noting the current PRIA date for the R350 action in my original email request. I am pasting the entire message in the body of this email to correct this date.

At this time Bayer is requesting the EPA extend our PRIA timeline of the action noted below for 9 months from August 30, 2015 to May 31, 2016:

Registration/Petition Numbers	Description of PRIA/IR-4 Actions	Decision Numbers
264-1025 (Belt SC Insecticide)	revise PHI in tobacco (R350) from 14 days to 1 day.	491208

Please let me know if you require further information to process this request.

Best Regards  
Nancy



**Bayer CropScience**  
Science For A Better Life

Nancy Delaney  
Federal Registrations  
Research Triangle Park, North Carolina, USA  
27709  
Phone: +1 919-549-2080  
Cell: 919-384-5957  
e-mail: [nancy.delaney@bayer.com](mailto:nancy.delaney@bayer.com)  
Web: [www.bayercropscience.ca](http://www.bayercropscience.ca)

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**From:** Nancy Delaney  
**Sent:** Wednesday, August 26, 2015 11:29 AM  
**To:** Rodia, Carmen  
**Cc:** Frank Ritemann; Charlotte Sanson; BCSReg\_Archive  
**Subject:** Action Required: request for approval to extend the PRIA timeline for Bayer's R350 action to revise PHI in tobacco



At this time Bayer is requesting the EPA extend our PRIA timeline of the action noted below for 9 months from August 31, 2015 to May 31, 2016:

Registration/Petition Numbers	Description of PRIA/IR-4 Actions	Decision Numbers
264-1025 (Belt SC Insecticide)	revise PHI in tobacco (R350) from 14 days to 1 day.	491208

Please let me know if you require further information to process this request.

Best Regards  
Nancy



**Bayer CropScience**  
Science For A Better Life

Nancy Delaney  
Federal Registrations  
Research Triangle Park, North Carolina, USA  
27709  
Phone: +1 919-549-2080  
Cell: 919-384-5957  
e-mail: [nancy.delaney@bayer.com](mailto:nancy.delaney@bayer.com)  
Web: [www.bayercropscience.ca](http://www.bayercropscience.ca)

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

June 10, 2015

I, Richard Gebken, Invertebrate and Vertebrate Branch 2, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Oman) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Bayer Cropscience Lp  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park, NC 27709

EPA Registration Number: 264-1025  
Name of Product: BELT SC INSECTICIDE

Richard Gebken  
Risk Manager 10  
Invertebrate and Vertebrate Branch 2  
Registration Division (7505P)





United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number  
Bayer CropScience LP

2. EPA Product Manager

Richard Gebken

3. Proposed Classification

☐ None☐ Restricted

4. Company/Product (Name)  
BELT SC Insecticide

PM#

10

5. Name and Address of Applicant (Include ZIP Code)

Natalie Mauchmar 2 T.W Alexander Drive Office 1177  
Durham, NC 27709



Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)  
(b)(i), my product is similar or identical in composition and labeling  
to:

EPA Reg. No. 264-1025

Product Name BELT SC Insecticide

## Section - II



Amendment - Explain below.

Final printed labels in response to  
Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_



"Me Too" Application.



Notification - Explain below.



Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Gold Seal Certificate for Oman

Thank you!!

## Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging



Yes\*



No

Unit Packaging



Yes



No

Water Soluble Packaging



Yes



No

2. Type of Container



Metal



Plastic



Glass



Paper



Other (Specify) \_\_\_\_\_

\* Certification must  
be submittedIf "Yes"  
Unit Packaging wgt.No. per  
containerIf "Yes"  
Package wgtNo. per  
container

3. Location of Net Contents Information



Label



Container

4. Size(s) Retail Container

5. Location of Label Directions



On Label



On Labeling accompanying product

6. Manner in Which Label is Affixed to Product

Lithograph  
Paper glued  
Stenciled

Other \_\_\_\_\_

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Natalie Mauchmar

Title

Labeling Specialist

Telephone No. (Include Area Code)

919-549-2550

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.  
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or  
both under applicable law.

2. Signature

3. Title

Labeling Specialist

4. Typed Name

Natalie Mauchmar

5. Date

05/27/2015

6. Date Application  
Received  
(Stamped)



# Receipt for Section 3

SI: 969376

Milestone Email:

Richard Gebken

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 264 BAYER CROSCIENCE LP



Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 10

Product #: 264-1025

Product Name: BELT SC INSECTICIDE

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 27-May-2015



OPP Rec'd Date: 04-Jun-2015



Front End Date: 04-Jun-2015



Risk Manager Send Date: 04-Jun-2015



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Gold Seal Certificate for Oman.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Other

Gold Seal

View/Edit

## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T)** U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34). [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**Section I** - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of direction for use"; "notification for...". Attach a separate page if additional space is needed.

**SECTION III** - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, amendment, reregistration, etc.

- 1-5. Self-explanatory
6. EPA Use Only



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 4, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-505623  
EPA File Symbol or Registration Number: 264-1025  
Product Name: BELT SC INSECTICIDE  
EPA Receipt Date: 04-Jun-2015  
EPA Company Number: 264  
Company Name: BAYER CROPSCIENCE LP

NATALIE MAUCHMAR  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, PO Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. H.", written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division



BNY MELLON, N.A.  
PITTSBURGH 15262



**Bayer**  
Pittsburgh, PA 15285

Contact for Questic  
1-866-283-6752

CHECK NO. 3200228078

60-160

433

PAY:

\*\*\*TWO HUNDRED SIXTY-THREE AND 00/100  
DOLLARS\*\*\*

\*  
\*  
\*  
\*

VOID 180 DAYS AFTER DATE OF CHECK

DATE: 05-29-15 \$\*\*\*\*\*263.00

TO  
THE  
ORDER  
OF

ENVIRONMENTAL PROTECTION AGENCY  
USEPA WASHINGTON FINANCE CENTER  
PESTICIDE REGISTRATION SERVICE  
PO BOX 979074  
ST. LOUIS MO 63197-9000

Authorized Signatures

*Gregory J. Spangol*  
*Daniel J. Alla*



⑈ 3 200 2 280 78 ⑈



**Bayer**  
Pittsburgh, PA 15285

Contact for Questions  
1-866-283-6752

PBC/528 BEPRW

VENDOR NO.	VENDOR NAME		DATE	CHECK NO.	CHECK AMOUNT
6768799	Environmental Protection Agency		05-29-15	3200228078	263.00
REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT	NET AMOUNT
IP27051510385393 Gold Seal Certificate	05-27-15	2400501467	263.00	0.00	263.00



Recommendation of Division Directors Negotiated Due Dates			
Decision #: 491208		Registration #: 264-1025	
		Petition #:	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Flubendiamide			
Fee Category: R350		PRIA Decision Time Frame: 90 Days	
Submitted by: Carmen		Rodia	Branch: OCSPP/OPP/RD      Date: 04/17/2015
Company: Bayer CropScience LP			
Original PRIA Due Date: 03/03/2015		Proposed New PRIA Due Date: 08/30/2015	
Previous Negotiated Due Dates: 06/01/2015			
Is the "Fix" in-house?		If not, date "Fix" expected:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a			
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Efficacy	<input type="checkbox"/> Toxicology <input type="checkbox"/> Ecological	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Residue <input type="checkbox"/> Environmental <input type="checkbox"/> Other
Data Deficiencies	<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Environmental	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Ecological	<input type="checkbox"/> Efficacy <input type="checkbox"/> Labeling <input type="checkbox"/> Residue <input type="checkbox"/> Other <input type="checkbox"/> Toxicology <input type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological		
Interim Consideration	<input type="checkbox"/> Agency Initiated <input checked="" type="checkbox"/> Registrant Initiated		
<input type="checkbox"/> CSF <input type="checkbox"/> Impurities Review	<input type="checkbox"/> Public Process <input type="checkbox"/> Label	<input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Risk Issues Human Health <input checked="" type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>			
Additional time is needed to continue discussion with Bayer CropScience LP related to the conditional registration of flubendiamide.			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): As a follow-up to an e-mail sent to Bayer CropScience LP on 04/16/2015, Carmen Rodia communicated with the registrant about the need for additional time (90 days) in order for the Agency to continue discussions with Bayer CropScience LP related to the conditional registration of flubendiamide.			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Additional time is needed to continue discussions with BCS.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature:    CN=Marty Monell/OU=DC/O=USEPA/C=US			Date:    04/21/2015

<b>Decision #:</b> 491208	<b>Registration #:</b> 264-1025	<b>Petition #:</b>

**Issue(s) (describe in detail):**

As a follow-up to an e-mail sent to Bayer CropScience LP on 04/16/2015, Carmen Rodia communicated with the registrant about the need for additional time (90 days) in order for the Agency to continue discussions with Bayer CropScience LP related to the conditional registration of flubendiamide. The registrant submitted a 90-day extension request (copy attached), which will change the existing PRIA conclusion date for the referenced R350 amendment from 06/01/2015 to 08/30/2015.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15107111405-CR

SUBMITTED on 04/17/2015 at 11:25:59 AM by CN=Carmen Rodia/OU=DC/O=USEPA/C=US

APPROVED on 04/17/2015 at 12:48:17 PM by CN=Deborah McCall/OU=DC/O=USEPA/C=US

APPROVED on 04/21/2015 at 09:17:14 AM by CN=Susan Lewis/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 04/21/2015 at 09:50:53 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

## Rodia, Carmen

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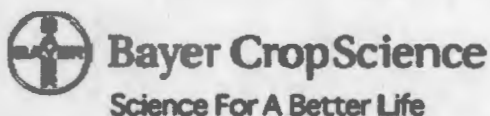
**From:** Nancy Delaney <nancy.delaney@bayer.com>  
**Sent:** Thursday, April 16, 2015 4:40 PM  
**To:** Rodia, Carmen  
**Cc:** McCall, Deborah; Gebken, Richard; Walsh, Michael; Charlotte Sanson; BCSReg\_Archive  
**Subject:** REQUEST FOR EXTENSION OF PRIA CONCLUSION DATE -- R350 Amendment for EPA Reg. No. 264-1025 (BELT SC Insecticide)

Good afternoon Carmen,

Bayer CropScience LP is agreeing to extend the PRIA conclusion date out 90 days for the R350 amendment submitted for EPA Reg. No. 264-1025 (BELT SC Insecticide) from June 1, 2015 to August 30, 2015. This 90-day extension of the PRIA conclusion date will allow the Agency to continue discussions with Bayer CropScience LP related to the conditional registration of flubendiamide.

Thank you in advance.

Best Regards,  
Nancy



Nancy Delaney  
Federal Registrations  
Research Triangle Park, North Carolina, USA  
27709  
Phone: +1 919-549-2080  
Cell: 919-384-5957  
e-mail: [nancy.delaney@bayer.com](mailto:nancy.delaney@bayer.com)  
Web: [www.bayercropscience.ca](http://www.bayercropscience.ca)

---

**From:** Rodia, Carmen [mailto:Rodia.Carmen@epa.gov]  
**Sent:** Thursday, April 16, 2015 10:32 AM  
**To:** Nancy Delaney  
**Cc:** McCall, Deborah; Gebken, Richard; Walsh, Michael  
**Subject:** REQUEST FOR EXTENSION OF PRIA CONCLUSION DATE -- R350 Amendment for EPA Reg. No. 264-1025 (BELT SC Insecticide)

Nancy, I am writing this e-mail to request that Bayer CropScience LP extend the previously extended PRIA conclusion date for the still pending R350 amendment to reduce the PHI for tobacco use for EPA Reg. No. 264-1025 (BELT SC Insecticide). The Agency is requesting additional time in order to continue discussions with Bayer CropScience LP related to the conditional registration of flubendiamide. You can use language similar to the following in order to facilitate the extension of the PRIA conclusion date:

"Bayer CropScience LP is agreeing to extend the PRIA conclusion date out 90 days for the R350 amendment submitted for EPA Reg. No. 264-1025 (BELT SC Insecticide) from June 1, 2015 to August 30, 2015. This 90-day extension of the

PRIA conclusion date will allow the Agency to continue discussions with Bayer CropScience LP related to the conditional registration of flubendiamide."

If you could, please submit Bayer CropScience LP's request for the extension of the PRIA conclusion for the referenced R350 amendment as soon as possible. Please contact me directly if you have any questions. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.  
Environmental Protection Specialist  
U.S. EPA, Office of Pesticide Programs,  
Registration Division, Invertebrate & Vertebrate Branch 2  
1200 Pennsylvania Avenue, NW (7504P)  
Washington, DC 20460-0001  
(703) 306-0327 (tel)  
(703) 308-0029 (fax)  
[Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov)

---

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

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Recommendation of Division Directors Negotiated Due Dates			
Decision #: 491208		Registration #: 264-1025	
<input type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Flubendiamide			
Fee Category: R350		PRIA Decision Time Frame: 90 Days	
Submitted by: Carmen		Rodia	Branch: OCSPP/OPP/RD      Date: 03/03/2015
Company: Bayer CropScience LP			
Original PRIA Due Date: 03/03/2015		Proposed New PRIA Due Date: 06/01/2015	
Previous Negotiated Due Dates:			
Is the "Fix" in-house?		If not, date "Fix" expected:	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> n/a			
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling
Late Risk Assessment	<input checked="" type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input checked="" type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input type="checkbox"/> Other – Comment Field
Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>			
Additional time is needed to complete the science review.			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
As a follow-up to an e-mail sent to Bayer CropScience LP on 03/03/2015, Carmen Rodia communicated with the registrant about the need for additional time (90 days) in order for the Agency to subsequently complete its science review to support the pending R350 amendment for EPA Reg. No. 264-1025 (BELT SC Insecticide).			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>			
Rationale for Proposed Due Date: Additional time is needed to complete the science review.			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US			Date: 03/04/2015

<b>Decision #:</b> 491208	<b>Registration #:</b> 264-1025	<b>Petition #:</b>

**Issue(s) (describe in detail):**

As a follow-up to an e-mail sent to Bayer CropScience LP on 03/03/2015, Carmen Rodia communicated with the registrant about the need for additional time (90 days) in order for the Agency to subsequently complete its science review to support the pending R350 amendment. The registrant submitted a 90-day extension request (copy attached), which will change the existing PRIA conclusion date for the referenced R350 amendment from 03/03/2015 to 06/01/2015.

**Comment(s):**



# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-15062164057-CR

SUBMITTED on 03/03/2015 at 04:53:09 PM by CN=Carmen Rodia/OU=DC/O=USEPA/C=US

APPROVED on 03/03/2015 at 04:56:41 PM by CN=Deborah McCall/OU=DC/O=USEPA/C=US

APPROVED on 03/03/2015 at 05:34:58 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 03/04/2015 at 07:09:02 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

## Rodia, Carmen

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**From:** Nancy Delaney <nancy.delaney@bayer.com>  
**Sent:** Tuesday, March 03, 2015 4:51 PM  
**To:** Rodia, Carmen  
**Cc:** McCall, Deborah; Gebken, Richard; BCSReg\_Archive  
**Subject:** Follow up: REQUEST FOR EXTENSION OF PRIA CONCLUSION DATE -- R350 Amendment for EPA Reg. No. 264-1025 (BELT SC Insecticide)

Good afternoon Carmen,

Bayer CropScience LP is agreeing to extend the PRIA conclusion date out 90 days for the R350 amendment submitted for EPA Reg. No. 264-1025 (BELT SC Insecticide) from March 3, 2015 to June 1, 2015. This will provide the Agency additional time to complete the pending science review necessary to support this R350 amendment.

Best Regards,

Nancy



**Bayer CropScience**  
Science For A Better Life

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Federal Registrations  
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e-mail: [nancy.delaney@bayer.com](mailto:nancy.delaney@bayer.com)  
Web: [www.bayercropscience.ca](http://www.bayercropscience.ca)

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**From:** Rodia, Carmen [mailto:Rodia.Carmen@epa.gov]  
**Sent:** Tuesday, March 03, 2015 4:33 PM  
**To:** Nancy Delaney  
**Cc:** McCall, Deborah; Gebken, Richard  
**Subject:** REQUEST FOR EXTENSION OF PRIA CONCLUSION DATE -- R350 Amendment for EPA Reg. No. 264-1025 (BELT SC Insecticide)

Nancy, as a follow-up to our phone call this afternoon, I am writing this e-mail to request that Bayer CropScience LP extend the PRIA conclusion date for the R350 amendment to reduce the PHI for tobacco use for EPA Reg. No. 264-1025 (BELT SC Insecticide). The Agency is requesting additional time to complete the pending science review required to support this pending PRIA action. You can use language similar to the following in order to facilitate the extension of the PRIA conclusion date:

"Bayer CropScience LP is agreeing to extend the PRIA conclusion date out 90 days for the R350 amendment submitted for EPA Reg. No. 264-1025 (BELT SC Insecticide) from March 3, 2015 to June 1, 2015. This will provide the Agency additional time to complete the pending science review necessary to support this R350 amendment."

If you could, please submit Bayer CropScience LP's request for the extension of the PRIA conclusion for the referenced R350 amendment as soon as possible. Please contact me directly if you have any questions. Regards, Carmen Rodia.

Carmen J. Rodia, Jr.  
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## Rodia, Carmen

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**From:** Rodia, Carmen  
**Sent:** Wednesday, March 04, 2015 11:55 AM  
**To:** Olinger, Christine  
**Cc:** McCall, Deborah; Gebken, Richard  
**Subject:** STATUS OF COMPLETION -- PRIA R350 Label Amendment for EPA Reg. No. 264-1025 (BELT SC INSECTICIDE)

Christine, I am writing to follow-up on the status of completion of an R350 PRIA action that was BEANed up to HED/RAB3 for flubendiamide on 08-26-2014. This R350 action was for HED to review one (1) volume of residue data on tobacco (MRID 49281201) submitted by Bayer CropScience LP in support of the registration for EPA Reg. No. 264-1025 (BELT SC INSECTICIDE). Bayer CropScience LP submitted this PRIA action in order to decrease the PHI for tobacco use from 14 days to 1 day. The PRIA conclusion date for this action was March 3, 2015. I just extended the PRIA conclusion date out 90 days to June 1, 2015 in order to give HED additional time to complete its review of this action. Could you please let us know when HED might be able to get this review completed. Thanks in advance. Regards, Carmen.

Carmen J. Rodia, Jr.  
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